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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

AFD 503

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on 5 JAN. 2006Signature Paul D HeydonTyped or printed name Paul D. Heydon

Application Number

10/828,630

Filed

04/09/2004

First Named Inventor

Jill E. Parker

Art Unit

1645

Examiner

Mark Navarro

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)☐ attorney or agent of record.
Registration number _____☒ attorney or agent acting under 37 CFR 1.34.Registration number if acting under 37 CFR 1.34 46,769Paul D Heydon
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5 JAN. 2006

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Appl. No.: 10/828,630
Request for Review of Final Rejection

Appl. No.: 10/828,630
Confirmation No.: 5340
Applicants: Jill E. Parker et al.
Filed: 04/09/2004
Title: Curlicue Vaccine Strain of Bacillus Anthracis
T.C./Art Unit 1645
Examiner: Mark Navarro
Docket No.: AFD 503
Customer No.: 26902

Commissioner for Patents
PO Box 1450
Alexandria VA 22313-1450

Request for Review of Final Rejection of October 6, 2005

Sir:

In response to the Final Rejection of October 6, 2005, the Assignee (Secretary of the Air Force) respectfully submits the following Request for Review.

Reasons for Request

Errors in Rejection: Claim 1

The assignee respectfully asserts that it was erroneous to reject Claim 1 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. A prima facie case of nonenablement has not been established.

A) As stated in MPEP 2164.04, "the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the

claimed invention. [Citing *In re Wright*] ... (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure)." The Final Rejection has failed to provide a reasonable explanation directed to the scope of rejected Claim 1 in this case: a "vaccine strain." The Final Rejection is improperly based on one word in Claim 1: "vaccine." This one word is improperly treated as if it were a red flag that prevents patenting.

B) As stated in MPEP 2164, "to comply with 35 U.S.C. 112, first paragraph, it is not necessary to 'enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect.'" [Citing *CFMT, Inc.*] The Final Rejection's insistence on prevention is an improper insistence on enabling a perfected, commercially viable embodiment. It is improper because Claim 1 does not describe a perfected, commercially viable embodiment. Claim 1 should be read in light of the following material in the Specification for example: "a vaccine strain of *Bacillus anthracis* that will *enable identification of new genes* that contribute to the pathogenesis of the organism and thereby elucidate new antigens that play a role in eliciting a specific, protective immune response early in the infection process." Specification Paragraph [0021][emphasis added]. (See further discussion at Pages 7-8 of Amendment and Reply to Office action of April 4, 2005.)

C) As stated in MPEP 2164.04, "References should be supplied if possible to support a prima facie case of lack of enablement ..." In this case, the Final

Rejection has not supplied a reference that supports a prima facie case of lack of enablement. The published application of Simonson, 20030143636A1, cited by the Final Rejection, is not relevant to the language of rejected Claim 1. The Simonson reference does not contain the phrase “vaccine strain” that is used in Claim 1. (See further discussion at Page 8 of Amendment and Reply to Office action of April 4, 2005.)

Errors in Rejection: New Claim 2

The Final Rejection fails to state a definite ground for objecting to or rejecting this claim. There is only a hypothetical, conditional ground for an objection, “should claim 1 be found allowable,” which has not happened. “Where a claim is refused for any reason relating to the merits thereof it should be “rejected” and the ground of rejection fully and clearly stated... The examiner should designate the statutory basis for any ground of rejection by express reference to a section of 35 U.S.C...” MPEP 707.07(d). In making a final rejection, “the examiner shall repeat or state all grounds of rejection ... clearly stating the reasons ...” 37 CFR § 1.113. Claim 2 is refused for some reason relating to the merits, but the ground of rejection is not fully and clearly stated. A prima facie case for rejection of Claim 2 has not been established.

Errors in Rejection: New Claims 3-4

It was erroneous to reject Claims 3-4, under 35 U.S.C. 102, as being anticipated by Ivins, US Pat. No. 6,387,665, and Keim, US Patent Application 20020055628A1. A prima facie case of anticipation has not been

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Request for Review of Final Rejection

established. As stated in MPEP 2131, to anticipate a claim, a reference must teach every element of the claim. The following are some limitations in the rejected claims which are not described in the references relied upon: thermal resistance (Claims 3 and 4), and delayed onset of death in a laboratory animal (Claim 4). The Examiner's references do not mention thermal resistance or delayed onset of death. Thus a prima facie case of anticipation has not been established.

In conclusion, the Final Rejection omits essential elements needed to make a prima facie case for rejection, concerning Claims 1-4. Assignee respectfully submits that the Final Rejection should be withdrawn, and requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,



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